EXHIBIT 9

EXPERT REPORT
DAVID KESSLER, M.D.

PART C: THE OPIOID MANUFACTURERS' MARKETING AND PROMOTION DEVIATED FROM FDA STANDARDS, INCREASING THE RISK OF ABUSE AND ENDANGERING PATIENT SAFETY

IV. PRIOR TO THE INTRODUCTION OF OXYCONTIN, HEALTHCARE PROVIDERS EXERCISED CAUTION IN PRESCRIBING STRONG OPIOIDS

67. For most of the 20th Century, American physicians approached prescribing opioids with caution,[49] believing opioids should not be used to manage chronic pain due to lack of evidence regarding their effectiveness and the risk of addiction.[50]

68. The abuse of opioids in the United States is not a new phenomenon. In 1803, Friedrich Wilhelm Adam Sertürner, a German chemist, isolated a substance from crude opium.[51] He named the substance morphine.[52] The widespread use of morphine during the American Civil War resulted in wave of opioid abuse and addiction.[53]

69. By the 1890s, medical textbooks and instructors regularly warned against overprescribing opioids,[54] and by the early 1900s the United States government sought to end the non-medicinal use of opium.[55] In 1909, Congress passed the Opium Exclusion Act, which barred the importation of opium for the purposes of smoking.[56] The Harrison Narcotics Act of

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[49] Phillips JK, Ford MA, Bonnie RJ. (2017). Pain Management and the Opioid Epidemic: Balancing Societal and Individual Benefits and Risks of Prescription Opioid Use. National Academies Press, *available at*: https://www.ncbi.nlm.nih.gov/books/NBK458661/Phillips.

[50] *Id.*

[51] *Id.*

[52] *Id.*

[53] Erick Trickey, *Inside the Story of America's 19th-Century Opiate Addiction*, Smithsonian Mag (Jan. 4, 2018), https://www.smithsonianmag.com/history/inside-story-americas-19th-century-opioids-addiction-180967673.

[54] *Id.*

[55] *The History of Opiates*, Michael's House, https://www michaelshouse.com/opiate-rehab/history-of-opiates/ (last visited Sept. 21, 2018).

[56] *Id.*

74. The lessons learned in the early 20th Century regarding the risks of opioid abuse were pushed aside by the aggressive marketing of a new generation of opioids starting in the 1990s, and opioid manufacturers' understatement of their risks and overstatement of their benefits as set forth below.

V. PURDUE

A. Overview

75. Purdue has promoted and sold various opioid products, including MS Contin and OxyContin.[72]

76. OxyContin is oxycodone in an extended release (ER) tablet, and oxycodone is a full opioid agonist that is relatively selective for the mu receptor.[73]

77. Purdue received initial FDA approval to market OxyContin on December 12, 1995. A discussion of subsequent labeling changes, including approval of OxyContin reformulated, is contained in Schedule 12.

78. In reviewing OxyContin, the FDA Medical Reviewer, Dr. Curtis Wright, IV, approached the review as evaluating an existing drug with a new dosage form. Oxycodone had been on the market as a stand-alone and combination drug that was administered every four to six hours. As noted in the above historical background section, the 1980s and 1990s saw the development of extended release delivery forms for a number of drug entities, including opioids. The review of the OxyContin NDA thus focused primarily on whether the twelve-hour administration was equivalent to the shorter acting immediate-release oxycodone formulation. The longest controlled clinical studies that were submitted as part of the OxyContin NDA were

[72] Other opioid products marketed by Purdue include Butrans, Dilaudid, Dilaudid-HP, Hysingla ER, Targiniq ER.

[73] PPLPC018001498098 at 3.

43. In my opinion, Mallinckrodt's sales training misleadingly minimized the risks associated with higher doses of opioids and encouraged sales representatives to make misleading claims regarding abuse deterrence.

44. In my opinion, Mallinckrodt misleadingly minimized the risk of addiction and funded the CARES Alliance which likewise understated the risk of addiction.

45. In my opinion, Mallinckrodt misleadingly told healthcare providers and trained its sales force that patients exhibiting signs of addiction were likely "pseudoaddicted" and in need of additional opioids to treat pain.

46. In my opinion, Mallinckrodt falsely marketed Xartemis as having a lower potential for abuse as compared to other opioid products.

47. In my opinion, through the pain advocacy group guidelines and materials they helped develop and disseminate, opioid manufacturers contributed to altering the standard of care for the treatment of pain by encouraging healthcare providers to view pain as a "fifth vital sign" that demanded aggressive treatment with opioids.

48. In my opinion, opioid manufacturers' support for and involvement with pain advocacy, professional medical and trade group organizations expanded the use of opioids and increased the risk of abuse.

49. In my opinion, the promotional violations discussed above endanger public health because they encourage the use of opioids in circumstances other than those in which the drugs have been approved, overstate their benefits and minimize their risks.

50. In my opinion, because the promotional violations discussed in this report are serious, corrective promotion and medical education that disseminates truthful, non-misleading,

and complete corrective messaging about the violations discussed above to the audiences that received the violative promotion is warranted.

51. In my opinion, the need for corrective promotion here is supported by research that has demonstrated that similar corrective promotion can be effective in countering false and misleading statements made about prescription drug products.

52. In my opinion, manufacturers should assure that no claims, including any superiority claims, about opioids are made without validation of those claims by high quality and well controlled clinical studies.

53. In my opinion, to correct the results of past practices, manufacturers should not fund treatment guidelines, organizations that issue treatment guidelines, or any authors of guidelines that concern pain, opioids or addiction. Disclosure of past and present funding from manufacturers to organizations and individuals that issue or author treatment guidelines should also be made.

54. Based on the totality of the above, it is my opinion that the manufacturers' departures from FDA standards would be expected to (and likely did) have an affect on how healthcare providers prescribed opioids, contributing to a shift in the practice of medicine with regards to the use of opioids in the treatment of pain. This change in the practice of medicine led to an increase in opioid prescriptions, an increase of opioids in interstate commerce, and an increase in inappropriate use of opioids, all of which in turn increased the risk of opioid abuse and contributed to a public health crisis.

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